Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR SIMPLIFIED AUTHORISATION APPLICATION**

submitted by the competent authority



ATTRACTIF GUEPES

Product type 19

 D-Fructose, Concentred apple juice, honey and acetic acid as included in the Annex I of Regulation (EU) No 582/2012

Case Number in R4BP: BC-JX066612-10

Competent Authority: FR CA

Date: 05/04/2022

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**Changes history table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **refMS/eCA** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment / renewal)** | **Chapter/ page** |
| SA-APP | FR | BC-JX066612-10 | 05/04/2022 | [Initial assessment] |  |

# Conclusion

ATTRACTIF GUEPES is a soluble concentrate biocidal product containing D-Fructose, honey, acetic acid and concentrated apple juice as active substances. The product is used as a PT19 by non-professionnals usersfor the control of wasps, hornets and flies.

The overall conclusion of the evaluation is that the biocidal product meets the conditions laid down in Article 25 of Regulation (EU) No 528/2012 and therefore can be authorised to control wasps, hornets and flies by non-professional users, as specified in the Summary of Product Characteristics (SPC). The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

**General**

Detailed information on the intended use of the biocidal product as applied for by the applicant and proposed for authorisation is provided in section 2.2 of the PAR.

Use-specific instructions for use of the biocidal product and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals and the environment are reported in sections 4 and 5 of the SPC.

Following evaluation, the biocidal product does meet the conditions required for simplified authorisation as defined in Article 25 of Regulation (EU) No 528/2012, i.e.:

1. The active substance acetic acid is listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that the concentration is limited so that the biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008”.

The active substances honey and D-fructose are listed in Annex I of Regulation (EU) 528/2012 and satisfy the restriction that honey/D-fructose are food or feed.

The active substance Concentrated apple juice is listed in Annex I of Regulation (EU) 528/2012 and satisfies the restriction concentrated apple juice does fall within the definition in point (2) of Part I of Annex I to Council Directive 2001/112/EC ”.

1. The biocidal product does not contain any substance of concern;
2. The biocidal product does not contain any nanomaterials;
3. The biocidal product is sufficiently effective;
4. The handling of the biocidal product as part of its intended use does not require any personal protective equipment (PPE).

A classification of the product ATTRACTIF GUEPES according to Regulation (EC) No 1272/2008[[1]](#footnote-2) is not necessary.

The biocidal product does not contain any non-active substances which are considered as substances of concern.

The biocidal product should be considered not to have endocrine-disrupting properties*.*

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

More information is available in section 2.7 of the PAR and in the confidential annex.

**Composition**

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturer(s) of the biocidal product is listed in section 1.4 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substances in the biocidal product are met. More information is available in sections 2.4 and 2.5 of the PAR. The manufacturers of the active substances are listed in section 1.5 of the SPC.

**Conclusions of the assessments for each area**

The intended uses as applied for by the applicant has been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. More information is available in section 3.2 of the PAR.

Physical hazards and respective characteristics

Physical hazards were not identified. More information is available in section 3.3 of the PAR.

Methods for detection and identification

Validated analytical methods for the determination of the active substances in the product are available. More information on the analytical methods for the active substance(s) is available in section 3.4 of the PAR.

No validated analytical methods are provided for monitoring of relevant components of the biocidal product and residues in soil, air, water, animal, and human body fluids, and in food and feeding stuff, because it is considered not necessary considering the identity of the active substances. More information is available in section 3.4 of the PAR.

Efficacy against target organisms

The efficacy of the biocidal product ATTRACTIF GUÊPES as an attractant has been shown against hornets (common hornet (*Vespa cabro*), Asian hornet (*Vespa velutina*), wasp (*Vespula vulgaris*), house flies (*Musca domestica*) and fruit flies *Drosophila spp* in traps filled with the product diluted at 23.81% v/v (125 mL product in 400 mL water).

More information is available in section 3.5 of the PAR.

Human health

No substances of concern regarding human health were identified.

The handling of the product and its intended use do not require personal protective equipment.

Environment

No substances of concern regarding environment were identified.

**Post-authorisation conditions**

None

# Information on the biocidal product

## Product type(s) and type(s) of formulation

Table 2.1 Product type(s) and type(s) of formulation

|  |  |
| --- | --- |
| **Product type(s)** | PT 19 |
| **Type(s) of formulation** | SL – Soluble concentrate |

## Uses

The intended uses as applied for by the applicant and the conclusions by the evaluating competent authority are provided in the table below. For detailed description of the intended uses and use instructions, refer to the respective sections of the SPC provided by the applicant. For detailed description of the authorised uses and use instructions, refer to the respective sections of the authorised SPC.

Table 2.2 Overview of uses of the biocidal product

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use number1** | **Use description2** | **PT3** | **Target organisms4** | **Application method5** | **Application rate6** **(min-max)** | **User category7** | **Conclusion****(eCA/ refMS)8** | **Comment (eCA/refMS)9** |
| 1 | Attractant  | PT 19 | Wasps, Hornets (common and Asian hornets), and Flies (including fruit flies) | Bait application | Dilution rate : 23,81% v/v (400 mL water and pour 125 mL of AttractifGuêpes) | Non-professional | A | Product efficient until 3 weeks. |

1 Use number (as applied for), as indicated in the SPC

2 Title of the specific use (as applied for), as indicated in the SPC

3 Product type(s) of the use(s)

4 Target organisms, group of organisms

5 Application method for the specific use

6 Min-max. application rate of the product for the specific use

7 User categor(y/ies), e.g. general public, non-professional, professional, industrial

8 eCA/refMS to indicate the acceptability for each use according to the below codes (Uses withdrawn by the applicant during evaluation will not be indicated in this table).

*Codes for indicating the acceptability for each use*

|  |  |
| --- | --- |
| A | Acceptable |
| R | Acceptable with further restriction or risk mitigation measures (RMM) |
| N | Not acceptable |

9 If the use is not acceptable or acceptable only with further restrictions, the eCA/refMS should indicate briefly the reason and indicate the section(s), e.g. phys-chem, efficacy, human health, environment, that the restriction is based upon.

## Identity and composition

The qualitative and quantitative information on the non-confidential composition of the biocidal product is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex of the PAR.

According to the information provided :

* The product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.
* All the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex.

## Identity of the active substance(s)

Table 2.3 Identity of the active substance(s)

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | D-Fructose |
| **Chemical name** | D-Fructose |
| **EC number** | *200-333-3* |
| **CAS number** | *57-48-7* |
| **Index number in Annex VI of CLP** | Not available |
| **Minimum purity / content** | *60%* |
| **Structural formula** |  |

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | Concentrated apple juice |
| **Chemical name** | Not applicable |
| **EC number** | Not applicable |
| **CAS number** | Not applicable |
| **Index number in Annex VI of CLP** | Not applicable |
| **Minimum purity / content** | Not applicable |
| **Structural formula** | Not applicable |

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | Honey |
| **Chemical name** | Honey |
| **EC number** | *Not applicable* |
| **CAS number** | *8028-66-8* |
| **Index number in Annex VI of CLP** | Not applicable |
| **Minimum purity / content** | *100%* |
| **Structural formula** | Not applicable |

|  |
| --- |
| **Main constituent(s)** |
| **Common name** | Acetic Acid |
| **Chemical name** | Acetic Acid |
| **EC number** | *200-580-7* |
| **CAS number** | *64-19-7* |
| **Index number in Annex VI of CLP** | Not applicable |
| **Minimum purity / content** | *80%v/v* |
| **Structural formula** |  |

## Information on the source(s) of the active substance(s)

The information on the sources of the active substances is not applicable.

## Candidate(s) for substitution

Not relevant

## Assessment of the endocrine-disrupting properties of the biocidal product

The biocidal product does not contain any active substances having endocrine-disrupting properties.

Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the biocidal product.

## Classification and labelling

Table 2.4 Classification and labelling of the biocidal product

|  | **Classification** | **Labelling** |
| --- | --- | --- |
| **Hazard Class and Category code** | *-* | - |
| **Hazard Pictograms** | *-* | - |
| **Signal word(s)**  | *-* | *-* |
| **Hazard statements** | *-* | *-* |
| **Precautionary statements\*** | - | - |
| **Supplemental hazard statements** | - |
| **Notes** |  |

##

## Letter of access

A Letter of Access is not applicable for products eligible for simplified authorisation under Article 25 of the BPR, for which the active substances are on Annex I of the BPR (category 4). The applicant is the owner of all submitted data.

## Data submitted in relation to product authorisation

*Please refer to section 4.3.*

# Assessment of the biocidal product

## Packaging

Table 3.1 Packaging

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging2** | **Material of thepackaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle  | 500 mL  | HDPE  | LDPE-PP Cap  | Non-professional  | Yes |
| Jerry can  | 2.5 L  | HDPE  | LDPE-PP Cap  | Non-professional  | Yes |

## Physical, chemical, and technical properties

Table 3.2 Physical, chemical, and technical properties

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa | VisualOrganoleptic | Attractif Guêpes  | Translucid liquidwith a vinegarodour | SDS of the product |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa |
| 3.1.2. | Colour at 20 °C and 101.3 kPa |
| 3.1.3. | Odour at 20 °C and 101.3 kPa |
| 3.2. | Acidity, alkalinity and pH value | Unknown  | Attractif Guêpes  | pH = 4  | SDS of the product |
| 3.3. | Relative density / bulk density | Not required as part of the simplified procedure. | Art.20(1)(b) of EU528/2012 |
| 3.4.1.1. | Storage stability test – **accelerated storage** | The product must be stored at a temperature ≤ 30°C  | SDS and label of theproduct |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | In accordance with the conclusions of the CG, the shelf-life ofthe product is set based on the available efficacy data on agedproduct.The shelf life of 36 months is supported by efficacy data. Thecurrent data shows the attractant effect remains unchangedafter 30 months of storage. To support the shelf-life of 36months, an additional efficacy test will be performed as soonas possible in 2022 on a sample aged at ambient temperaturein the commercial packaging. | Minutes CG-30meeting related tostorage stability insimplifiedauthorisationrequests. |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** | The product should be stored at a temperature > 0°C.  | SDS and label of theproduct |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** | Not determined as the product is packed in opaquepackagings, so that effects of light can be excluded. |  |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - Effect of temperature: not determined as the product must bestored at a temperature > 0°C and ≤ 30°C.- Effect of humidity: negligeable as the commercial packagingsare hermetically sealed, leak-tight and the product containswater. | - |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Refer to the sections on the storage stability tests | - |
| 3.5.1. | Wettability  | Not applicable. The product is a soluble concentrate | - |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability  | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.3. | Wet sieve analysis and dry sieve test  | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability  | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.5. | Disintegration time | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability  | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.7. | Persistent foaming  | Not required as part of the simplified procedure.  | Art.20(1)(b) of EU528/2012 |
| 3.5.8. | Flowability/pourability/dustability | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.9. | Burning rate — smoke generators | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.10. | Burning completeness — smoke generators | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.11. | Composition of smoke — smoke generators | Not applicable. The product is a is a soluble concentrate | - |
| 3.5.12. | Spraying pattern — aerosols / spray | Not applicable. The product is a is a soluble concentrate | - |
| 3.6.1. | Physical compatibility | Not applicable. The product is not intended to be used inconjunction with any other products or active substances. | - |
| 3.6.2. | Chemical compatibility | Not applicable. The product is not intended to be used inconjunction with any other products or active substances. | - |
| 3.7. | Degree of dissolution and dilution stability  | Not required as part of the simplified procedure.  | Art.20(1)(b) of EU528/2012 |
| 3.8. | Surface tension  | Not required as part of the simplified procedure.  | Art.20(1)(b) of EU528/2012 |
| 3.9. | Viscosity  | Not required as part of the simplified procedure.  | Art.20(1)(b) of EU528/2012 |

Table 3.3 Conclusion on physical, chemical, and technical properties

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| --- |
| **Conclusion on physical, chemical, and technical properties** |
| ATTRACTIF GUEPES is a translucid liquid with a vinegar odour. Its pH is expected to be around 4 (pure).The product must be stored at a temperature > 0°C and ≤ 30°C. As per CG-30 (2018), it was agreed that - in the case of a simplified authorisation - the shelf-life of a product could be set based on either efficacy data or long term chemical storage stability data at ambient temperature. Accordingly, storage stability data is deemed not necessary in the case of the shelf-life being supported by efficacy data. For this product, the shelf life was determined by available efficacy trials on aged product. **Implications for labelling**: store at a temperature > 0°C and ≤ 30°C  |

## Physical hazards and respective characteristics

Table 3.4 Physical hazards and respective characteristics

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product / batch (AS% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 4.1. | Explosives | The four active substances in the product are included in Annex I of the BPR and thus are not expected to give rise to concern regarding explosiveness. They have no explosive properties according to their safety/technical datasheets. In addition, the major active substance in the product is D-fructose; this ingredient has no chemical group associated with explosive properties. Moreover, none of the co-formulants is expected to have explosive properties according to their chemical structure. And due to their low contents in the product, they are not considered as being able to lead to a classification of the product. As a result, the product Attractif Guêpes is not expected to be explosive and test is considered as unnecessary. | Art. 28(2)(a) of theBPR andSDS/TDS of activesubstances and coformulants. |
| 4.2. | Flammable gases | Not applicable. The product is a liquid. | - |
| 4.3. | Flammable aerosols | Not applicable. The product is not an aerosol |  | - |
| 4.4. | Oxidising gases | Not applicable. The product is a liquid. |  | - |
| 4.5. | Gases under pressure | Not applicable. The product is a liquid. |  | - |
| 4.6. | Flammable liquids | The four active substances contained in the product are included in Annex I of the BPR.D-fructose, concentrated apple juice and honey are not expected to give rise to any concern regarding flammability according to their safety/technical datasheets. The major active substance in the product is D-fructose; this ingredient, found in many plants (fruits, vegetables), has no flammable properties. The ingredient Acetic acid 80% Vol. is not classified as flammable according to its safety datasheet (flash point > 60°C); acetic acid is therefore not expected to be flammable at 1.262% w/w (pure content in the product Attractif Guêpes). In addition, none of the co-formulants, is classified as flammable according to their safety/technical datasheets. Therefore, the product Attractif Guêpes is not expected to be flammable andflash point test is considered as unnecessary. | Art. 28(2)(a) of theBPR andSDS/TDS of activesubstances and coformulants |
| 4.7. | Flammable solids | Not applicable. The product is a liquid. |  |  |
| 4.8. | Self-reactive substances and mixtures | The four active substances contained in the product are included in Annex I of the BPR and thus are not expected to give rise to concern regarding self-reactive properties. They have no self-reactive properties according to their safety/technical datasheets. The major active substance in the product is fructose; this ingredient, found in many plants (fruits, vegetables) is not classified as self-reactive. In addition, none of the co-formulants is expected to have self-reactive properties according to their chemical structure. Moreover, due to their low contents in the product, they are not considered as being able to lead to a classification of the product. Therefore, the product Attractif Guêpes is not expected to present selfreactive properties and test is considered as unnecessary. | SDS/TDS of activesubstances and coformulants. |
| 4.9. | Pyrophoric liquids | Test is not required as the product does not contain any components classified as pyrophoric according to their safety/technical data sheets. Moreover, experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. The product Attractif Guêpes is not expected to be a pyrophoric liquid and test is not required | SDS/TDS of activesubstances and coformulants. |
| 4.10. | Pyrophoric solids | Not applicable. The product is a liquid |  |
| 4.11. | Self-heating substances and mixtures | Not applicable. The product is a liquid | SDS/TDS of activesubstances and coformulants |
| 4.12. | Substances and mixtures which in contact with water emit flammable gases | Not classified. The product is a water based product and does not react with water | - |
| 4.13. | Oxidising liquids | Not classified. None of the components in the mixture is classified for oxidising properties, therefore the product is also not classified for oxidising properties | SDS/TDS of activesubstances and coformulants. |
| 4.14. | Oxidising solids | Not applicable. The product is a liquid. |  |
| 4.15. | Organic peroxides | The active substances are included in Annex I of the BPR and thus should not give rise to concern regarding organic peroxides. The product Attractif Guêpes is not concerned by the physical hazard“organic peroxides” as its components are not organic peroxides and are not expected to form any organic peroxides | Art. 28(2)(a) of theBPR andSDS/TDS of activesubstances and coformulants. |
| 4.16. | Corrosive to metals | C.1 UN Test of UNManual of Tests andCriteria(exposure time: 7 days at 55°C)Product AttractifGuêpesBatch number: 3605containing- 48.819 % w/w Dfructose- 1.924 % w/wconcentrated applejuice- 1.540 % w/w honey- 1.577 % w/w aceticacid | The product Attractif Guêpes is notconsidered to be corrosive to steel andaluminium. Neither localised nor uniformcorrosion was observed after the test; the test item Attractif Guêpes isnot classified as corrosive to metalsaccording to Regulation EC No. 1272/2008(CLP) and C.1 UN Test of UNManual of Tests andCriteria | Padilla P.,Défitraces, 2021Report No. 21-919062-008 |
| 4.17.1. | Auto-ignition temperatures of products (liquids and gases) | EU Method A.15NF T 20-037Product AttractifGuêpesBatch number: 3605Containing - 48.819 % w/w Dfructose- 1.924 % w/wconcentrated applejuice- 1.540 % w/w honey- 1.577 % w/w aceticacid | The auto-ignition temperature of the product Attractif Guêpes was 402 ± 3°C (corrected temperature) | Padilla P.,Défitraces, 2021Report No. 21-919062-008 |
| 4.17.2. | Relative self-ignition temperature for solids | Not applicable. The product is a liquid. |  |
| 4.17.3. | Dust explosion hazard | Not applicable. The product is a liquid |  |

Table 3.5 Conclusion on physical hazards and respective characteristics

|  |
| --- |
| **Conclusion on physical hazards and respective characteristics** |
| The product ATTRACTIF GUEPES does not present a significant hazard for explosive properties, flammability, self-reactivity, self-heating properties, oxidising properties, corrosivity to metals and autoinflammability. Some tests could be waived according to the composition of the product, to the safety or technical datasheets of its ingredients and their chemical structure. According to the test results, it is not corrosive to metals. Its auto-ignition temperature is 402 ± 3°C.Therefore, no classification and labelling for physical hazards is required for ATTRACTIF GUEPES |

## Methods for detection and identification

Table 3.6 Analytical methods for the analysis of the product as such including the active substance, impurities, and residues

|  |
| --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities, and residues** |
| Principle of the method: D-fructose and D-glucoseD-fructose determination is based on enzymatic analysis according to D-fructose and D-glucose kit (KFRUGL 04/18 Megazyme) using spectrophotometry by absorbance at 340 nm. D-fructose determination is based on enzymatic reaction. The analytical method is sequential, so the fructose is measured after the glucose measurement: D-glucose and D-fructose are phosphorylated by the enzyme hexokinase (HK) in the presence of adenosine-5’-triphosphate (ATP) to glucose-6-phosphate (G-6-P) and fructose-6-phosphate (F-6-P) with the simultaneous formation of adenosine-5’-diphosphate (ADP).D-glucose + ATP --(enzyme HK)--> glucose-6-phosphate + ADPD-fructose + ATP --(enzyme HK)--> fructose-6-phosphate + ADP In the presence of the enzyme glucose-6-phosphate dehydrogenase (G6P-DH), G-6-P is oxidised by nicotinamide-adenine dinucleotide phosphate (NADP+) to gluconate-6-phosphate with the formation of reduced nicotinamide-adenine dinucleotide phosphate (NADPH). glucose-6-phosphate + NADP+ --(enzyme G6P-DH)--> gluconate-6-phosphate + NADPH + H+ .The amount of NADPH (measured with spectrophotometers at 340 nm) formed in this reaction isstoichiometric with the amount of D-glucose. On completion of this last reaction, F-6-P is converted to G-6-P by phosphoglucose isomerase (PGI).F-6-P --(enzyme PGI)--> G-6-P. The G-6-P formed reacts in turn with NADP+ forming gluconate-6-phosphate and NADPH, leading to a further rise in absorbance that is stoechiometric with the amount of D-fructose.Measurements are done with spectrophotometer at 340 nm. acetic acid Acetic acid determination is based on enzymatic reaction: Acetic acid is converted by the enzyme acetate kinase (AK) in the presence of adenosine-5’-triphosphate (ATP) into acetyl-phosphate with the simultaneous formation of adenosine-5’-diphosphate (ADP). acetic acid + ATP --(enzyme AK)--> acetyl-phosphate + ADP. This reaction is significantly accelerated by the rapid conversion of the acetyl-phosphate product into acetyl-CoA and inorganic phosphate, by the action of phosphotransacetylase (PTA) in the presence of coenzyme A (CoA).acetyl-phosphate + CoA --(enzyme PTA)--> acetyl-CoA + PiThe ADP formed in the first reaction is reconverted into ATP and pyruvate, by phosphoenolpyruvate (PEP) in the presence of pyruvate kinase (PK).ADP + PEP --(enzyme PK)--> pyruvate + ATPIn the presence of the enzyme D-lactate dehydrogenase (D-LDH), pyruvate is reduced to D-lactate by reduced nicotinamide-adenine dinucleotide (NADH) with the production of NAD+.pyruvate + NADH + H+ --(enzyme D-LDH)--> D-lactate + NAD+The amount of NAD+ formed in the above reaction pathway is stoichiometric with the amount of acetic acid. It is NADH consumption which is measured by the decrease in absorbance at 340 nm |
| **Analyte** (type of analyte e.g. active substance) | **Linearity** | **Specificity** | **Fortification range, level and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of Quantification LOQ** *– only for impurit(y/ies)* | **Reference** |
| Level | Number of measurements | Range | Mean | RSD | Concentration tested | Number of replicates |
| D-fructose | Calibration range: from 1.08 µg to 5.41 µg D-fructose (equivalent to 33.27% -166.33% w/w D-fructose in the formulated product):y = 0.0877 \* x – 0.0014 (y = average of corrected absorbances at340 nm, x = Dfructose amount (in µg)r = 0.9999 (n>5) | *Blank formulation degree of interference was observed. It contributes to less than 3% of test article**absorbance*  | 15%w/w | 3 | 91-107% | 97.3 | 8.74 | 50.31% RSD: 1.46%Horrat<1 (0.98) | 5 | / | GLP Analytical method validation according to SANCO 3030/99 rev.5 for D-fructose determination in the biocidal product “Attractif Guêpes”, Andreu V. 2021, Report no.: 2021-02\_BPL02 |
| D-glucose | Calibration range: from 1.035 µg to 6.210 µg D-glucose (equivalent to 2.6% - 15.4%w/w D-glucose in the formulated product):y = 0.0856 \* x + 0.0005 (y = average of corrected absorbances at 340 nm, x = Dglucose amount (in µg)r = 0.9999 (n>5) | *Blank formulation degree of interference was observed. It contributes to less than**3% of test article absorbance* | 1.5%w/w  | 3 | 97-101% | 99 | 2.02 | 8.33% RSD: 1.62%Horrat<1 (0.83) | 5 |  | GLP Analytical method validation according to SANCO 3030/99 rev.5for D-glucose determination in the biocidal product “Attractif Guêpes”Andreu V.2021Report no.: 2021-02\_BPL01 |
| Acetic acid | Calibration range: from 3.78 µg to 18.90 µg acetic acid (equivalent to 0.74% - 3.69%w/w acetic acid in the formulated product):y = 0.0528 \* x – 0.0282 (y = average of corrected absorbances at 340 nm, x = aceticacid amount (in µg/mL)r = 0.9989 (n>5) | Blank formulation degree of interference was observed. It contributes to less than3% of test article absorbance | 0.75%w/w | 2 | 90-110% | 92 | - | 1.27% RSD: 2.44%Horrat<1 (0.94) | 5 |  | GLP Analytical method validation according to SANCO 3030/99 rev.5for acetic acid determination in the biocidal product “Attractif Guêpes, Andreu V 2021, 2021-02\_BPL03 |

Table 3.7 Analytical methods for soil

|  |
| --- |
| **Analytical methods for soil** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
| - | - | - | - |  |  |  |  |  | - | - |

Table 3.8 Analytical methods for air

|  |
| --- |
| **Analytical methods for air** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity** | **Specificity** | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
| - | - | - | --- | - | - | - | - | - | - | - |

Table 3.9 Analytical methods for water

|  |
| --- |
| **Analytical methods for water** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity**  | **Specificity**  | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits**  | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
| - | - | - | - | - | - | - | - | - | - | - |

Table 3.10 Analytical methods for animal and human body fluids and tissues

|  |
| --- |
| **Analytical methods for animal and human body fluids and tissues** |
| **Analyte (type of analy**te e.g. active substance)**Analytical method** | **Linearity**  | **Specificity**  | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits**  | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
| - | - | - | - | - | - | - | - | - | - | - |

Table 3.11 Analytical methods for monitoring of active substances and residues in food and feeding stuff

|  |
| --- |
| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| **Analyte** (type of analyte e.g. active substance)**Analytical method** | **Linearity**  | **Specificity**  | **Fortification range, level, and number of measurements at each level** | **Recovery rate (%)** | **Precision (%)** | **Limit of quantification (LOQ) or other limits**  | **Reference** |
| Range | Mean | RSD | Concentration tested | Number of replicates |
| - | - | - | - | - | - | - | - | - | - | - |

Table 3.12 Conclusion on methods for detection and identification

|  |
| --- |
| **Conclusion on methods for detection and identification**  |
| Analytical methods have been validated according to SANCO 3030/99 rev. 5 for determining D-fructose, D-glucose and acetic acid contents in the biocidal product ATTRACTIF GUEPES by definition of the specificity, the linearity, the accuracy and the precision of the methods and Guidelines requirements were fulfilled. Indeed, the Annex I active substances D-fructose, concentrated apple juice and honey contain D fructose. Since it is not possible to distinguish between the different sources of D-fructose in the product ATTRACTIF GUEPES, the total amount of D-fructose in the product was determined. As the other main component of honey is D-glucose, this content was also determined in the product ATTRACTIF GUEPES. In addition, D-fructose, D-glucose and acetic acid contents were determined in the fructose syrup, concentrated apple juice, honey and “acetic acid 80%” in order to identify the origin of D-fructose, D-glucose and acetic acid in the biocidal product ATTRACTIF GUEPES. D-fructose, D-glucose and acetic acid dosages were performed with enzymatic methods using spectrophotometry by absorbances at 340 nm.According to analytical results, the product Attractif Guêpes contains 50.31% w/w D-fructose, 8.33% w/w D-glucose and 1.27% w/w acetic acid.Analytical methods for monitoring active substances residues in soil, air, water, human body fluids and tissues are no data requirement for simplified procedures according to Article 20(1)(b) of the BPR. There are no available analytical methods for D-fructose, concentrated apple juice, honey and acetic acid residues in soil, air, water, and human body fluids and tissues. Analytical methods for monitoring active substances residues in food/feed of plant and animal origins are no data requirement for simplified procedures according to Article 20(1)(b) of the BPR.There are no available analytical methods for D-fructose, concentrated apple juice, honey and aceticacid residues in food/feed of plant and animal origins |

##

## Assessment of efficacy against target organisms

### Function (organisms to be controlled) and field of use (products or objects to be protected)

The product ATTRACTIF GUÊPES is an attractant liquid intended to be used in traps against wasps, flies and hornets, for outdoor use. The product is used to attract these targets in traps which are source of nuisance through their stings and their presence near food.

The product is used to protect human health and food.

### Mode of action and effects on target organisms, including unacceptable suffering

The flies, wasps and hornets are attracted by the product insides the trap. The insects drown into the liquid in the trap. It is an olfactory attraction.

##

### Efficacy data

Efficacy studies have been performed with the product ATTRACTIF GUEPES. Results are presented in the table below

Table 3.13 Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **PT and use number** | **Test product** | **Function / Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects***[address here results related to efficacy of the test product and validity of the test]* | **Reference**  | **Number in IUCLID section 6.7/Test report title** |
| PT19Use 1: Attractant | Attractif Guêpes Batch 2283(fresh product) | Attractant:WaspCommon hornetAsian hornetHouse flies Fruits flies | Field trialTest system + concentration applied:125 mL product + 400 mL water in a trap- 2 test sites TN01 (approx.. 4 000 m²) and TN02 (approx.. 8000 m²)- 5 traps in each site = 4 traps with the product (4 different traps type in site TN01 and 4 identical traps in site TN02) +1 control trap with only water.Distance between traps higher than 10 m.Testing period:- 5 testing periods of 21 days each (from April to August 2019)Assessments:For the assessment, each trap was emptied on a rigid filter. The insects were sorted and counted and then returned to the trap with the liquid for until the end of the testing period of 21 days.Assessment were performed 24 hours after setting up the traps on the test sites, and then 4, 7, 11, 14, 18 and 21 days after. | * In the control devices (only water), very few insects were caught:

- For the test site 1, one bee and one fly were caught in July, 14 days after the beginning of the testing period-For the test site 2, two moths were caught during the testing period of July and two moths and one fly were caught during the testing period of August.* In the treated traps:

Below the total number of insects trapped per site per 21 days periods over the whole testing period from April to August:For the test site 1, it can also be shown that no significant difference between the different traps in terms of numbers and types of insects caught was observed. Repartition of the trapped insects on the test site one, for the different traps over the 5 periods of 21 days:Conclusion:The product ATTRACTIF GUÊPES showed a good attractant efficacy against house flies, fruit flies, wasps, common hornets and Asian hornets when used in trap when diluted at 23.81% v/v (125 mL product in 400 mL water), in comparison with the water control.All the targets caught are killed.It also showed a very good selectivity as only 2 bees were caught for the test site 1 and no one on test site 2, over the testing periods from April to August. | Moraiti, 2021Test 2019RI=1 | 6.7-01 |
| PT19Use 1: Attractant | Attractif Guêpes Batch 2283(15 month old product) | Attractant:WaspCommon hornetAsian hornetHouse flies Fruits flies | Field trialTest system + concentration applied:125 mL product + 400 mL water in a trap- 2 test sites TN01 (approx. 4 000 m²) and TN02 (approx.. 8000 m²)- 5 traps in each site = 4 traps with the product (4 different traps type in site TN01 and 4 identical traps in site TN02) +1 control trap with only water.Distance between traps higher than 10 m.Testing period:- 5 succeeding testing periods of 21 days each (from April to August 2019)Assessments:For the assessment, each trap was emptied on a rigid filter. The insects were sorted and counted and then returned to the trap with the liquid for until the end of the testing period of 21 days.Assessment are performed 24 hours after setting up the traps on the test sites, and then 4, 7, 11, 14, 18 and 21 days after. | * In the control devices (water only), very few insects were caught:

 -For the test site 1, one fly was caught in July and in August, 14 days after the beginning of the testing period -For the test site 2, no insect was caught during the testing period.* In the treated traps:

Below the total number of insects trapped per site per 21 days periods over the whole testing period from April to August:For the test site 1, where different traps were used, it can also be shown that no significant differences between the different traps in terms of numbers and types of insects caught were observed.Repartition of the trapped insects on the test site one, for the different traps over the 5 periods of 21 days:Conclusion:This study confirmed that the product ATTRACTIF GUÊPES 15 months aged remained efficient as attractant against house flies, fruit flies, wasps, common hornets and Asian hornet when used in trap, diluted at 23.81% v/v (125 mL product in 400 mL water), in comparison with the water control.It also shows a good selectivity as only 2 bees for the site 1 and 1 bee for the site 2 were caught over the test periods from April to August. | Moraiti, 2021Test 2020RI=1 | 6.7-02 |
| PT19Use 1: Attractant | Attractif concentréBatch 2283(30 months aged product)(identical to a ATTRACTIF GUÊPES)Attractif guêpeBatch 3257(fresh product (5 months) | Attractant:WaspCommon hornetAsian hornetFlies Fruits flies | Field trialTest system + concentration applied:125mL product + 400 mL of water in one bait design.4 peri-urban sites in Italy:A public park, an hospital green area, a private urban apiary and a buffer strip where wasps and hornets were observed.For each site, 4 traps are set at a distance of 12 meters. Each trap was activated with a different attractant (aged product, fresh product, water control, blank control (aged product without the a.s.). Traps are rotated at each assessment.Testing period:18th July – 08th August.Assessments:For the assessment, each trap was emptied on a rigid filter. The insects are sorted and counted and then were returned to the trap with the liquid for until the end of the testing period (21 days). A wing is cut off for each captured insect to avoid recording again.Assessment are performed 24 hours after setting up the traps on the test sites, and then 4, 7, 14 and 21 days after. | Total number of insects trapped (21 days trapping, 4 replicates)For wasps:No statistical difference was found between the fresh and aged formulation neither between the two controlsFor hornets:No statistical difference was found between the fresh and aged formulation neither between the two controls.For hornet, the main species trapped was Vespa cabro but Vespa velutina were also captured in a less proportion.For flies:A statistical difference was found between the fresh and aged formulation (more flies were caught with the old formulation). No statistical difference was found between the two controlsFor flies, mainly 4 families were identified (sarcophagidae, calliphoridae, muscidae and drosophilidae)Conclusion:The product ATTRACTIF concentré 30 months aged remained efficient as attractant against flies, fruit flies, wasps, common hornets and Asian hornets when used in trap, diluted at 23.81% v/v (125 mL product in 400 mL water), , in comparison with the controls.It also show a good selectivity as only 4 bees for the aged formulation and no bees for the fresh product were caught over the test period.It should be noted that 35 and 37 bees were caught respectively in the water control and in the blank control. | A. Drago 2021RI=1 | 6.7-03 |

### Efficacy assessment

Two field trials have been performed with the product ATTRACTIF GUÊPES on the same sites (one residential site in Mouriès (France) and one unexploited apple orchard (but still producing apples) in Maussane-les–Alpilles (France), in 2019 with a fresh formulation and 2020 with a 15 month aged formulation.

The product was tested during 21 days over a period from April to August.

On the first test site, different trap designs were used. The choice of the trap was based on the most common traps available on the market. For the second site only one trap design was used.

From the results, it appeared that the design of the trap has no impact on the observed efficacy as on the residential site, no significant difference was observed in the number and type of targets trapped in the different trap designs.

It should be highlighted that the product demonstrated a good selectivity as only one bee was trapped during the duration.

These studies showed the attractant efficacy of the product ATTRACTIF GUÊPES fresh and 15 months aged against house flies, fruit flies, wasps, common hornets and Asian hornet when used in trap, diluted at 23.81% v/v (125 mL product in 400 mL water), , in comparison with the water control.

An additional field trial has been performed with several items, a 30 month aged product ATTRACTIF CONCENTRE (identical to ATTRACTIF GUÊPES),a fresh product (ATTRACTIF GUÊPES), a blank formulation (product without the active substances) and a water control.

4 traps (one for each conditions) where set for the 4 sub-urban sites tested.

The product was tested during 21 days in mid-July-August.

This study showed that no coformulant has an impact on the efficacy of the product. Indeed no statistical difference was noted between the water control and the blank formulation.

This study showed the attractant efficacy of the product ATTRACTIF GUÊPES fresh and 30 months aged against flies, fruit flies, wasps, common hornets and Asian hornet when used in trap, diluted at 23.81% v/v (125 mL product in 400 mL water), in comparison with the water control.

Regarding the shelf-life of the product, no preservative is present in the composition of the product. As a 30 months aged product was tested with a successful efficacy, then based on the TAB v2.2 2020, a shelf-life of 30 months can be validated.

### Conclusion on efficacy

Based on the efficacy data presented, it can be concluded that the product ATTRACTIF GUÊPES is efficient to attract hornets (common hornet (*Vespa cabro*), Asian hornet (*Vespa velutina*), wasp (*Vespula vulgaris*), flies (including house flies (*Musca domestica*), fruit flies *Drosophila spp*) in traps filled with the product diluted at 23.81% v/v (125 mL product in 400 mL water).

The product should be renewed in the trap every 3 weeks.

### Occurrence of resistance and resistance management

The target organisms are attracted by the active ingredients which are food sources for these insects. All the target organisms caught get killed by drowning therefore occurrence of resistance is not expected.

### Known limitations

*None*

### Relevant information if the product is intended to be authorised for use with other biocidal products

The product ATTRACTIF GUEPES is not intended to be used in combination with other biocidal products

## Human health

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

### Assessment of effects on human health

There are no human health data available for the product. The assessment, and classification and labelling are based on the agreed endpoints for the active substances and available information for the non-active substances.

The classification of the product ATTRACTIF GUEPES has been set according to the calculation rules laid down in the CLP regulation 1272/2008/EC.

The biocidal product ATTRACTIF GUEPES is not classified for skin corrosion and irritation, eye irritation, respiratory tract irritation, skin sensitization, respiratory sensitization and acute toxicity.

#### Skin corrosion and irritation

Table 3.17 Conclusion used in Risk Assessment – Skin corrosion and irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not classified as skin corrosive or irritant. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product. |
| Classification of the product according to CLP  | No classification is required. |

Table 3.18 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Skin corrosion or irritation |
| Justification | The active substance Acetic acid is present in the product at a concentration below the specific concentration limit to classify the product Skin Corr. 1B, H314 or Skin Irrit. 2, H315. |

#### Eye irritation

Table 3.22 Conclusion used in Risk Assessment – Eye irritation

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not classified as Eye irritant. |
| Justification for the value/conclusion | Based on intrinsic properties of individual components of the product. |
| Classification of the product according to CLP  | No classification required. |

Table 3.23 Data waiving

|  |
| --- |
| **Data waiving** |
| Information requirement | Eye irritation |
| Justification | The active substance Acetic acid is present in the product at a concentration below the specific concentration limit to classify the product Eye Irrit. 2, H319. |

### Available toxicological data relating to substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfil the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)).

### Available toxicological data relating to endocrine disruption

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

### 3.6.4. Dietary exposure

Active substances are listed in Annex I of Regulation (EU) No 528/2012. Moreover, considering the uses, food, or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substances is considered as negligible.

## Animal health

Not relevant

## 3.8. Environment

According to Article 25 and Article 20(1)(b) of Regulation (EU) No 528/2012, it only has to be assessed whether the product fulfils all conditions for a simplified authorisation procedure.

### Classification

Classification of the product has been calculated according to the classification rules for mixtures according to CLP Regulation (EC) N° 1272/2008 and the product is not classified.

Moreover there is no need for risk mitigation measure to protect the environment.

###  Substance(s) of concern

The product ATTRACTIF GUEPES does not contain any environmental substance of concern (SoC) according to the EU guidance on SoC (Article 3(f) of the BPR, Guidance on BPR, Volume IV, Part B+C, version 2.0-2017).

### Screening for endocrine disruption relating to non-target organisms

For the assessment of endocrine-disrupting properties of the non-active substances, refer to the respective section of the confidential annex.

## 3.9. Assessment of a combination of biocidal products

The biocidal product ATTRACTIF GUEPES is not intended to be used with other biocidal products.

## 3.10. Comparative assessment

As active substances are listed in Annex I of Regulation (EU) No 528/2012, a comparative assessment is not relevant.

# Appendices

## New information on the active substance(s) and substance(s) of concern

No new information on the active substances is available

No new information on the substances of concern is available

## List of studies for the biocidal product

Table 4.3 List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section N° IUCLID** | **Author** | **Year** | **-Title****-Source (laboratory)****-Report N°****-Report date****-GLP; (un)published** | **Data protection (Y/N)** | **Owner** |
| 4.16,4.17 | Padilla P. | 2021 | * Auto-ignition temperature of liquids and test methods for corrosion to metals on ATTRACTIF GUÊPES
* Défitraces (Brindas, France)

- 21-919062-008- 2021-10-26* GLP; unpublished
 | Y | Spring |
| 5.1.1 | Andreu V. | 2021 | * GLP Analytical method validation according to SANCO 3030/99 rev.5 for D-fructose determination in the biocidal product “Attractif Guêpes”
* Akinao (Perpignan, France)

- 2021-02\_BPL02- 2021-05-21* GLP; unpublished
 | Y | Spring |
| 5.1.2 | Andreu V. | 2021 | * GLP Analytical method validation according to SANCO 3030/99 rev.5 for D-glucose determination in the biocidal product “Attractif Guêpes”
* Akinao (Perpignan, France)

- 2021-02\_BPL01- 2021-05-21* GLP; unpublished
 | Y | Spring |
| 5.1.3 | Andreu V. | 2021 | * GLP Analytical method validation according to SANCO 3030/99 rev.5 for acetic acid determination in the biocidal product “Attractif Guêpes”
* Akinao (Perpignan, France)

- 2021-02\_BPL03- 2021-05-21* GLP; unpublished
 | Y | Spring |
| 5.1.4 | Andreu V. | 2021 | * Dosage of D-Glucose, D-Fructose and acetic acid in 4 active substances of the biocidal product “Attractif Guêpes”
* Akinao (Perpignan, France)

-2021-02-2021-05-25* non-GLP; unpublished
 | Y | Spring |
| 6.7\_01 | Moraiti O. | 2021 | * Field efficacy of the product ATTRACTIF GUEPES. Year 2019
* Internal test
* 2019\_Attractif Guêpes

- 2021-05-05* Non GLP; unpublished
 | Y | Spring |
| 6.7\_02 | Moraiti O. | 2021 | * Field efficacy of the product ATTRACTIF GUEPES. Year 2020
* Internal test
* 2020\_Attractif Guêpes

- 2021-05-05 | Y | Spring |

## Confidential information

Please refer to the separate document Confidential Annex of the PAR.

1. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [↑](#footnote-ref-2)